K091185

1. 510(k) Summary

In accordance with 21 CFR section 807.92 Hsiner is submitting the following 510(k) summary.

1.1. Submitter Information

Hsiner Company, LTD
No.312, Jhongshan Rd., Shengang Township,
Taichung County 429
Taiwan, ROC

Phone: +86-4-25152480

JUL 24 2009

Registration No.: 3003862188
Owner/Operator No.: 9053474

1.2. Name of Device

Device Name:	Filter, Bacterial, Breathing-Circuit
Product Code:	CAH
Regulation #:	868.5260
Device Class:	2

1.3. Substantially equivalent to:

- Hudson RCI Bacterial/Vial Filter (961914)
- Gibeck Humid Vent filter Compact (K964382)

1.4. Description of the device

The BFE/VFE filters, manufactured by Hsiner, ITD are disposable, single-use barrier type, bi-directional devices supplied to the customer packaged and non-sterile. These filter devices are fabricated with a filtering medium that is highly effective at reducing the numbers of both bacterial and viral contaminates present in a patient's exhaled gas. The devices are designed to minimize the resistance to air flow. They consist of two molded plastic housings enclosing a disk of filter media. The Hsiner filtered HME device also includes a reticulated foam that captures heat and moisture from the patient's breath.

1.5. Intended Use of the Device

Disposable single patient use bidirectional filters used to reduce the possible bacterial and/or viral cross contamination of ventilatory and anesthesia equipment associated valves and hoses, from aerosols and particulates, which may be present in a patient's exhaled gas. These devices are intended for use on all patient populations to filter respiratory gases where infection from airborne bacteria and viruses is a concern.

1.6. Comparison to Predicate Devices

The Hsiner Reusable Filters are equivalent in design and performance to the Hudson RCI Bacterial/Viral Filter and the Gibeck Humid Vent Filter Compact.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Hsiner Company, Limited
C/O Mr. Tom Shanks
Principal
MDVentures
29201 Via Norte
Temecula, California 92591

JUL 24 2009

Re: K091185
Trade/Device Name: Hsiner 70530, 70536 Filters and 70531 Filtered HME
Regulation Number: 21 CFR 868.5260
Regulation Name: Breathing Circuit Bacterial Filter
Regulatory Class: II
Product Code: CAH
Dated: July 13, 2009
Received: July 21, 2009

Dear Mr. Shanks:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

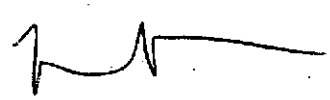
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/cdrh/mdr/ for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,



Kwame Ulmer, M.S.
Acting Associate Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (K091185):

Device Name: Hsiner 70530, 70536 Filters and 70531 Filtered HME

Indications for Use:

Disposable single patient use bidirectional filters used to reduce the possible bacterial and/or viral cross contamination of ventilatory and anesthesia equipment associated valves and hoses, from aerosols and particulates, which may be present in a patient's exhaled gas. These devices are intended for use on all patient populations to filter respiratory gases where infection from airborne bacteria and viruses is a concern.

Prescription Use ___X___ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Anesthesiology, General Hospital
Infection Control, Dental Devices

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